RULES
OF
DEPARTMENT OF HEALTH
BOARD FOR LICENSING HEALTH CARE FACILITIES
DIVISION OF HEALTH CARE FACILITIES

CHAPTER 1200-8-34
STANDARDS FOR HOME CARE ORGANIZATIONS PROVIDING PROFESSIONAL SUPPORT SERVICES

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1200-8-34-.01 DEFINITIONS.

(1) Administrator. A person who establishes policies and procedures and is responsible for the activities of the agency and its staff. This person may be a physician, registered nurse, therapist, or a person with at least one (1) year experience in a health or disability related field. The administrator of a home care organization may serve as both a home health agency and professional support service agency administrator if both agencies are owned by the same corporation or legal entity.

(2) Advance Directive. A written statement such as a living will, a durable power of attorney for health care, or a do not resuscitate order relating to the provision of health care when the individual is incapacitated.

(3) Agency. A home care organization providing professional support services.

(4) Analysis. A process for identifying the most basic or causal factor or factors that underlie variation in performance leading to an unusual event. The analysis must contain the following analytical processes: the proximate cause of the unusual event, an analysis of systems and processes involved in the unusual event, identification of possible common causes, identification of potential improvements, the plan of correction or action plan, and measures of effectiveness.

(5) Board. The Tennessee Board for Licensing Health Care Facilities.

(6) Clinical Note. A written and dated notation containing a consumer assessment, responses to medications, treatments, services, any changes in condition and signed by a health team member who made contact with the consumer.

(7) Commissioner. The Commissioner of the Tennessee Department of Health or his or her authorized representative.

(8) Competent. A consumer who has decision-making capability.

(9) Comprehensive Nursing assessment. An assessment conducted by a registered nurse which consists of four parts: completion of a Physical Status Review (PSR); consumer and family history; identification of health concerns, functional abilities, activities of daily living; and, completion of a head to toe physical assessment.

(Rule 1200-8-34-.01, continued)

(10) Consumer. Any person with a primary diagnosis of mental retardation or developmental disability served through the Division of Mental Retardation Services or the Department of Mental Health and Developmental Disabilities in need of nursing, occupational, physical or speech therapy through a professional support service agency.

(11) Corrective Action Plan/Report. A report filed with the department by the agency after reporting an unusual event. The report must consist of the following:

(a) the action(s) implemented to prevent the reoccurrence of the unusual event,

(b) the time frames for the action(s) to be implemented,

(c) the person(s) designated to implement and monitor the action(s), and

(d) the strategies for the measurements of effectiveness to be established.

(12) Department. The Tennessee Department of Health.

(13) Hazardous Waste. Materials whose handling, use, storage and disposal are governed by local, state or federal regulations.

(14) Individual Support Plan (ISP). The document resulting from a process of person-centered planning. The ISP describes in detail the person, including his/her vision for his/her future, preferences, non-negotiables, and other information required to support the person in daily life. The ISP contains outcomes to be achieved with the assistance of the person's Circle of Support that relate to the person's vision for the future. The ISP is written upon a person's enrollment in Department of Mental Retardation Services and updated thereafter as changes occur in the individual's life, or at least annually.

(15) Infectious Waste. Solid or liquid wastes which contain pathogens with sufficient virulence and quantity such that exposure to the waste by a susceptible host could result in an infectious disease.

(16) Legal Guardian. Any person authorized to act for the patient pursuant to any provision of T.C.A. Title 34, Chapters 1 through 3 and 5.

(17) Licensed Practical Nurse. A person currently licensed as such by the Tennessee Board of Nursing.

(18) Licensee. The person or entity to whom the license is issued. The licensee is held responsible for compliance with all rules and regulations.

(19) Life Threatening or Serious Injury. Injury requiring the consumer to undergo significant additional diagnostic or treatment measures.

(20) Medical Record. Medical histories, records, reports, clinical notes, summaries, diagnoses, prognoses, records of treatment and medication ordered and given, entries and other written electronic, or graphic data prepared, kept, made or maintained in an agency that pertains to confinement or services rendered to consumers. The medical record shall meet the standards established in the contractual agreement between the state agency financially responsible for services to individuals with mental retardation or developmental disabilities.

(21) Occupational Therapist. A person currently licensed as such by the Tennessee Board of Occupational and Physical Therapy Examiners.

(Rule 1200-8-34-.01, continued)

(22) Occupational Therapy Assistant. A person currently licensed as such by the Tennessee Board of Occupational and Physical Therapy Examiners.

(23) Patient/Consumer Abuse. Patient/consumer neglect, intentional infliction of pain, injury, or mental anguish. Patient/consumer abuse includes the deprivation of services by a caretaker which are necessary to maintain the health and welfare of a patient or consumer; however, the withholding of authorization for or provision of medical care to any terminally ill person who has executed an irrevocable living will in accordance with the Tennessee Right to Natural Death Law, or other applicable state law, if the provision of such medical care would conflict with the terms of such living will shall not be deemed "patient/consumer abuse" for purposes of these rules.

(24) Physical Status Report (PSR). An instrument used by a registered nurse or other designated professional staff to determine level of risk and define the required health services and supports.

(25) Physical Therapist. A person currently licensed as such by the Tennessee Board of Occupational and Physical Therapy Examiners.

(26) Physical Therapy Assistant. A person currently licensed as such by the Tennessee Board of Occupational and Physical Therapy Examiners.

(27) Physician. A person currently licensed as such by the Tennessee Board of Medical Examiners or currently licensed as such by the Tennessee Board of Osteopathic Examination.

(28) Plan of Care. Health care plan resulting from the comprehensive nursing assessment and/or therapy plan identifying the need for nursing, physical, occupational, or speech therapy for consumers of professional support services. The plan shall meet the standards established in the contractual agreement between the state agency financially responsible for services to individuals with mental retardation or developmental disabilities.

(29) Professional Support Services. Nursing, occupational, physical or speech therapy services provided to individuals with mental retardation or developmental disabilities pursuant to a contract with the state agency financially responsible for such services.

(30) Registered Nurse. A person currently licensed as such by the Tennessee Board of Nursing.

(31) Shall or Must. Compliance is mandatory.

(32) Site Code. An approved location from which the professional support services may be provided as deemed by the Department of Mental Retardation Services with written notice provided to the Department of Health by the professional support service agency for each site code approved for such agency.

(33) Speech Language Pathologist. A person currently licensed as such by the Tennessee Board of Communication Disorders and Sciences or, for purposes of these rules, a Speech Language Pathologist who is currently in their Clinical Fellowship Year.

(34) Supervision. Authoritative procedural guidance by a qualified person for the accomplishment of a function or activity with initial direction and periodic inspection of the actual act of accomplishing the function or activity. Periodic supervision must be provided if the person is not a licensed or certified assistant, unless otherwise provided in accordance with these rules.

(Rule 1200-8-34-.01, continued)

(35) Unusual Event. The abuse of a consumer or an unexpected occurrence or accident that results in death, life threatening or serious injury to a consumer that is not related to a natural course of the consumer's illness or underlying condition.

(36) Unusual Event Report. A report form designated by the department to be used for reporting an unusual event.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-201, 68-11-202, and 68-11-209.* ***Administrative History:*** *Original rule filed January 24, 2003; effective April 9, 2003.*

1200-8-34-.02 LICENSING PROCEDURES.

(1) No person, partnership, association, corporation, or state, county, or local government unit, or any division, department, board or agency thereof, shall establish, conduct, operate or maintain in the State of Tennessee any home care organization providing professional support services without having a license. A license shall be issued to the person or persons named and for the premises listed in the application for licensure. The name of the agency shall not be changed without first notifying the department in writing. Licenses are not transferable or assignable and shall expire annually on June 30th. The license shall be conspicuously posted in the agency.

(2) In order to make application for a license:

(a) The applicant shall submit an application on a form prepared by the department.

(b) Home care organizations authorized to provide only professional support services shall pay an annual fee of eight hundred dollars ($800.00), except that this annual fee shall be two hundred dollars ($200.00) for (i) home care organizations that also pay a fee to be licensed by the department of mental health and developmental disabilities; (ii) home care organizations owned and operated by therapists who pay a fee to be licensed under Title 63, Chapter 13 or 17; or (iii) home care organizations that are owned and controlled by another home care organization that pay an annual license fee of at least eight hundred dollars ($800.00). The fee must be submitted with the application and is not refundable.

(c) The issuance of an application form is in no way a guarantee that the completed application will be accepted or that a license will be issued by the department. Consumers shall not be admitted to the agency until a license has been issued. Applicants shall not hold themselves out to the public as being an agency until the license has been issued. A license shall not be issued until the agency is in substantial compliance with these rules, including submission of all information required by T.C.A. §68-11-206(1) or as later amended, and all information required by the Commissioner.

(d) The applicant must prove the ability to meet the financial needs of the agency providing professional support services.

(e) The applicant shall not use subterfuge or other evasive means to obtain a license, such as filing for a license through a second party when an individual has been denied a license or has had a license disciplined or has attempted to avoid inspection and review process.

(3) A proposed change of ownership must be reported to the department a minimum of thirty (30) days prior to the change. A new application and fee must be received by the department before the license may be issued.

(Rule 1200-8-34-.02, continued)

(a) For the purposes of licensing, the licensee of an agency has the ultimate responsibility for the operation of the agency, including the final authority to make or control operational decisions and legal responsibility for the business management. A change of ownership occurs whenever this ultimate legal authority for the responsibility of the agency's operation is transferred.

(b) Circumstances constituting a change of ownership may include, but are not limited to, the following:

1. Partnership. In the case of a partnership, the removal, addition, or substitution of a partner constitutes a change of ownership. If the agency is owned by a limited partnership, the removal of the general partner or general partners constitutes a change of ownership.

2. Corporation. The merger of an agency owner into another corporation, or the consolidation of two or more corporations resulting in the creation of a new corporation, constitutes a change of ownership. Transfer of corporate stock (even when a controlling interest), or the merger of another corporation into the originally-licensed corporation does not constitute a change of ownership.

3. Leasing. The lease of an agency's operations constitutes a change of ownership. Sale/lease-back agreements shall not be treated as changes of ownership if the lease involves the agency's entire real and personal property and if the identity of the lessee, who shall continue the operation, retains the exact same legal form as the former owner.

4. Transfers. Transfer of an agency's legal title, or a transfer between levels of government constitutes a change of ownership. A transfer between departments of the same level of government does not constitute a change of ownership.

5. Management agreements are generally not changes of ownership if the owner continues to retain ultimate authority for the operation of the agency. However, if the ultimate authority is surrendered and transferred from the owner to a new manager, then a change of ownership has occurred.

(4) To be eligible for a license or renewal of a license, each agency shall be periodically inspected for compliance with these regulations. If deficiencies are identified, an acceptable plan of correction shall be established and submitted to the Department.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-216.* ***Administrative History:*** *Original rule filed January 24, 2003; effective April 9, 2003. Amendment filed May 27, 2004; effective August 10, 2004.*

1200-8-34-.03 DISCIPLINARY PROCEDURES.

(1) The Board may suspend or revoke a license for:

(a) Violation of federal or state statutes;

(b) Violation of the rules as set forth in this chapter;

(c) Permitting, aiding or abetting the commission of any illegal act in the agency or the consumer's home; or

(Rule 1200-8-34-.03, continued)

(d) Conduct or practice found by the Board to be detrimental to the health, safety, or welfare of the consumers of the agency.

(2) The Board may consider all factors which it deems relevant, including but not limited to the following when determining sanctions:

(a) The degree of sanctions necessary to ensure immediate and continued compliance;

(b) The character and degree of impact of the violation on the health, safety and welfare of the consumer of the agency;

(c) The conduct of the agency in taking all feasible steps or procedures necessary or appropriate to comply or correct the violation; and

(d) Any prior violations by the agency of statutes, rules or orders of the Board.

(3) Inappropriate transfers are prohibited and violation of the transfer provisions shall be deemed sufficient grounds to suspend or revoke an agency's license.

(4) When an agency is found by the Department to have committed a violation of this chapter, the Department will issue to the agency a statement of deficiencies. Within ten (10) days of receipt of the statement of deficiencies the agency must return a plan of correction indicating the following:

(a) How the deficiency will be corrected;

(b) The date upon which each deficiency will be corrected;

(c) What measures or systemic changes will be put in place to ensure that the deficient practice does not recur; and

(d) How the corrective action will be monitored to ensure that the deficient practice does not recur.

(5) Either failure to submit a plan of correction in a timely manner or a finding by the department that the plan of correction is unacceptable shall subject the agency's license to possible disciplinary action.

(6) Any licensee or applicant for a license, aggrieved by a decision or action of the department or Board, pursuant to this chapter, may request a hearing before the Board. The proceedings and judicial review of the Board's decision shall be in accordance with the Uniform Administrative Procedures Act, T.C.A. §§4-5-101, et seq.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, and 68-11-206 through 68-11-209.* ***Administrative History:*** *Original rule filed January 24, 2003; effective April 9, 2003.*

1200-8-34-.04 ADMINISTRATION.

(1) The home care organization providing professional support services must organize, manage and administer its services to attain and maintain the highest practicable functional capacity for each consumer regarding nursing and therapy needs as indicated by the plan of care.

(2) The agency shall develop and maintain administrative control of any site code.

(3) The organizational structure, professional support services provided, administrative control and lines of authority for the delegation of responsibility down to the consumer care level shall be clearly set

forth in writing and shall be readily identifiable. Administrative and supervisory functions shall not be delegated to another agency.

(4) A governing body (or designated person(s) so functioning) must: assume full legal authority and responsibility for the management and provision of all professional support services; fiscal operations; quality assessment and performance improvement programs. The governing body shall appoint a qualified administrator who is responsible for the day-to-day operation of the organization and is responsible for designating people to carry out these functions.

(5) The administrator shall organize and direct the organization's ongoing functions, the professional personnel and the staff; employ qualified personnel and ensure adequate staff education and evaluation for all personnel involved in direct care; ensure the accuracy of public information materials and activities; and implement an effective budgeting and accounting system. A person with sufficient experience and training shall be authorized in writing to assume temporary duty during the administrator's short-term absence. The designee may be a physician, registered nurse, or a therapist.

(6) An agency shall have a duly qualified administrator accessible during normal operating hours. Any change of administrators shall be reported to the Department within fifteen (15) days.

(7) The administrator of a home care organization may serve as both a home health agency and professional support service agency administrator if both agencies are owned by the same corporation or legal entity.

(8) The agency shall maintain an office with a working telephone that is staffed or takes voice messages during normal business hours.

(9) When licensure is applicable for a particular position of employment, a copy of the current license or the number and renewal number of the employee's current license must be maintained in the employee's personnel file. Each personnel file shall contain accurate information as to the education, training, experience and personnel background of the employee. Proof of adequate medical screenings to exclude communicable disease shall be maintained in the file of each employee.

(10) Personnel practices shall be supported by written personnel policies. Personnel records shall include at a minimum: job descriptions, verification of references and credentials, and performance evaluations. Personnel records must be kept current. Agencies employing only one (1) staff member must maintain a personnel record with verification of current credentials.

(11) An ongoing educational program shall be planned and conducted for the development and improvement of skills of all the agency's personnel engaged in delivery of professional support services. Each employee shall receive appropriate orientation to the agency, its policies, the employee's position, and the employee's duties. Records shall be maintained which indicate the subject of and attendance at such staff development programs.

(12) If personnel, under hourly or per visit contracts, are utilized by the agency, there shall be a written contract between such personnel and the agency clearly designating:

(a) That consumers are accepted for care only by the agency;

(b) Which professional support services are to be provided;

(c) That it is necessary to conform to all applicable agency policies including personnel qualifications;

(Rule 1200-8-34-.04, continued)

(d) The responsibility for participating in developing plans of care;

(e) The manner in which professional support services will be controlled, coordinated and evaluated by the agency;

(f) The procedures for submitting clinical and progress notes, scheduling visits and periodic consumer evaluations; and

(g) The procedures for determining charges and reimbursement.

(13) Supervision of unlicensed personnel must occur at a minimum of every thirty (30) days and must include direct observation of the provision of care, record review and individual conferences.

(14) Whenever the rules of this chapter require that a licensee develop a written policy, plan, procedure, technique or system concerning a subject, the licensee shall develop the required policy, maintain it and adhere to its provisions. An agency which violates a required policy also violates the rule establishing the requirement.

(15) Policies and procedures shall be consistent with professionally recognized standards of practice.

(16) All agencies shall adopt appropriate policies regarding the testing of consumers and staff for human immunodeficiency virus (HIV) and any other identified causative agent of acquired immune deficiency syndrome.

(17) No agency shall retaliate against or, in any manner, discriminate against any person because of a complaint made in good faith and without malice to the Board, the Department, the Department of Human Services Adult Protective Services, the state agency financially responsible for services to consumers, or the Comptroller of the State Treasury. An agency shall neither retaliate nor discriminate because of information lawfully provided to these authorities, because of a person's cooperation with them or because a person is subpoenaed to testify at a hearing involving one of these authorities.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-222.* ***Administrative History:*** *Original rule filed January 24, 2003; effective April 9, 2003.*

1200-8-34-.05 ADMISSIONS, DISCHARGES, AND TRANSFERS.

(1) Consumers shall be accepted to receive professional support services on the basis of a reasonable expectation that the consumer's nursing and therapy needs can be met adequately by the agency.

(2) Professional support services shall be provided as prescribed by the attending physician. The plan for providing professional support services and the expected outcomes shall be incorporated into the consumer's plan of care or individual support plan.

(3) The agency staff shall determine if the consumer's needs can be met by the agency's services and capabilities.

(4) Every person admitted for professional support services by any agency covered by these rules shall be provided services as prescribed by the consumer's physician, as defined in this chapter, who holds a license in good standing. The name of the consumer's attending physician shall be recorded in the consumer's medical record.

(Rule 1200-8-34-.05, continued)

(5) The agency staff shall obtain the consumer's or his/her designee's written consent for professional support services.

(6) The signed consent form shall be included with the consumer's individual clinical record.

(7) A diagnosis must be entered in the admission records of the agency for every person admitted for care or treatment.

(8) No medication or treatment shall be provided to any consumer of an agency except on the order of a physician lawfully authorized to give such an order.

(9) A medical record shall be developed and maintained for each consumer admitted.

(10) The agency's discharge planning process, including discharge policies and procedures, must be in writing and follow the guidelines established in the written agreement between the agency and the Division of Mental Retardation Services (DMRS). If the agency determines that they are no longer willing or able to provide services, they must comply with the following:

(a) Prior to discontinuation of authorized services, the agency shall obtain approval from the DMRS;

(b) The agency shall notify the consumer, their conservator or guardian, the support coordinator, and DMRS no less than sixty (60) days prior to the planned discharge;

(c) If the consumer or his/her representative request an appeal in accordance with T.C.A. §33-2-601, et seq., the discharge will not occur prior to the final agency decision and resolution of the administrative appeal unless ordered by a court and approved by the state;

(d) The agency shall continue to provide services until the consumer is provided with other services that are of acceptable and appropriate quality in order to maintain continuity of care; and

(e) If the consumer or his/her representative request to be discharged from the agency, the agency will follow the steps as outlined above and provide transfer documentation to new provider, if requested, in order to maintain continuity of care and facilitate transfer.

(11) The agency shall ensure that no person on the grounds of race, color, national origin or handicap, will be excluded from participation in, be denied benefits of, or otherwise subjected to discrimination in the provision of any care or service of the agency. The agency shall protect the civil rights of residents under the Civil Rights Act of 1964 and Section 504 of the Rehabilitation Act of 1973.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, and 68-11-209.* ***Administrative History:*** *Original rule filed January 24, 2003; effective April 9, 2003.*

1200-8-34-.06 BASIC AGENCY FUNCTIONS.

(1) All personnel providing professional support services shall assure that their efforts effectively complement other services provided to the consumer, are functionally integrated into the individual daily routine and support the outcome outlined in the individual support plan. A written report of progress shall be provided to the consumer's support coordinator/case manager monthly. A written summary report for each consumer shall be sent to the attending physician at least annually.

(2) Plan of Care.

(Rule 1200-8-34-.06, continued)

(a) The written plan of care, developed in consultation with the agency staff, shall cover all pertinent diagnoses, including mental status, types of services and equipment required, frequency of services, prognosis, rehabilitation potential, functional limitations, activities permitted, nutritional requirements, medications and treatments, any safety measures to protect against injury, instructions for timely discharge or referral, and any other appropriate items. If a physician refers a consumer under a plan of care which cannot be completed until after an evaluation visit, the physician shall be consulted to approve additions or modifications to the original plan. Orders for professional support services shall include the specific treatment or modalities to be used and their amount, frequency and duration. The therapist and other agency personnel shall participate in developing the plan of care.

(b) The plan(s) of care for acute or episodic illness shall be reviewed by the attending physician and agency personnel involved in the consumer's care as often as the severity of the consumer's condition requires, but at least annually. Plans of care resulting from Comprehensive Nursing Assessment will be reviewed in accordance with the physical status review schedule. Evidence of review by the physician must include the physician's signature and date of the review on the plan of care. A facsimile of the physician's signature is acceptable. Professional staff shall promptly alert the physician to any changes that suggest a need to alter the plan of care.

(3) Drugs and treatments shall be administered by appropriately licensed agency personnel, acting within the scope of their licenses. Orders for drugs and treatments shall be signed and dated by the physician.

(4) Skilled Nursing Services.

(a) When skilled nursing is provided, the services shall be provided by or under the supervision of a registered nurse who has no current disciplinary action against his/her license, in accordance with the plan of care. This person shall be available at all times during operating hours and participate in all activities relevant to the professional support services provided, including the development of qualifications and assignment of personnel.

(b) The registered nurse's duties shall include but are not limited to the following: make the initial evaluation visit, except in those circumstances where the physician has ordered therapy services as the only skilled service; regularly evaluate the consumer's nursing needs; initiate the plan of care and necessary revisions; provide those services requiring substantial specialized nursing skill; initiate appropriate preventive and rehabilitative nursing procedures; prepare clinical and progress notes; coordinate services; inform the physician and other personnel of changes in the consumer's condition and needs; counsel the consumer and family in meeting nursing and related needs; participate in in-service programs; supervise and teach other nursing personnel. The registered nurse or appropriate agency staff shall initially and periodically evaluate drug interactions, duplicative drug therapy and non-compliance to drug therapy.

(c) The licensed practical nurse shall provide services in accordance with agency policies, which may include but are not limited to the following: prepare clinical and progress notes; assist the physician and/or registered nurse in performing specialized procedures; prepare equipment and materials for treatments; observe aseptic technique as required; and assist the consumer in learning appropriate self-care techniques.

(5) Therapy Services.

(a) All therapy services offered by the agency directly or under arrangement shall be planned, delegated, supervised or provided by a qualified therapist in accordance with the plan of care. A qualified therapist assistant may provide therapy services under the supervision of a qualified therapist in accordance with the plan of care. The therapist shall assist the physician in

evaluating the level of function, helping develop the plan of care (revising as necessary), preparing clinical and progress notes, advising and consulting with the family and other agency personnel, and participating in in-service programs.

(b) Speech therapy services shall be provided only by a licensed speech language pathologist in good standing or speech language pathologist in the Clinical Fellowship Year under the supervision of a licensed speech language pathologist.

(6) Performance Improvement.

(a) An agency shall have a committee or mechanism in place to review, at least annually, past and present professional support services including contract services, in accordance with a written plan, to determine their appropriateness and effectiveness and to ascertain that professional policies are followed in providing these services.

(b) The objectives of the review committee shall be:

1. To assist the agency in using its personnel and facilities to meet individual and community needs;

2. To identify and correct deficiencies which undermine quality of care and lead to waste of agency and personnel resources;

3. To help the agency make critical judgments regarding the quality and quantity of its services through self-examination;

4. To provide opportunities to evaluate the effectiveness of agency policies and when necessary make recommendations to the administration as to controls or changes needed to assure high standards of consumer care;

5. To augment in-service staff education, when applicable;

6. To provide data needed to satisfy state licensure and certification requirements;

7. To establish criteria to measure the effectiveness and efficiency of the professional support services provided to consumers; and

8. To develop a record review system for the agency to evaluate the necessity or appropriateness of the professional support services provided and their effectiveness and efficiency.

(7) Infection Control.

(a) There must be an active performance improvement program for developing guidelines, policies, procedures and techniques for the prevention, control and investigation of infections and communicable diseases.

(b) Formal provisions must be developed to educate and orient all appropriate personnel and/or family members in the practice of aseptic techniques such as handwashing and scrubbing practices, proper hygiene, use of personal protective equipment, dressing care techniques, disinfecting and sterilizing techniques, and the handling and storage of consumer care equipment and supplies.

(Rule 1200-8-34-.06, continued)

(c) Continuing education shall be provided for all agency consumer care providers on the cause, effect, transmission, prevention and elimination of infections, as evidenced by the ability to verbalize/or demonstrate an understanding of basic techniques.

(d) The agency shall develop policies and procedures for testing a consumer's blood for the presence of the hepatitis B virus and the HIV (AIDS) virus in the event that an employee of the agency, a student studying at the agency or other health care provider rendering services at the agency is exposed to a consumer's blood or other body fluid. The testing shall be performed at no charge to the consumer, and the test results shall be confidential.

(e) The agency and its employees shall adopt and utilize standard precautions (per CDC) for preventing transmission of infections, HIV and communicable diseases.

(f) Precautions shall be taken to prevent the contamination of sterile and clean supplies by soiled supplies. Sterile supplies shall be packaged and stored in a manner that protects the sterility of the contents.

(8) Medical Records.

(a) A medical record containing past and current findings in accordance with accepted professional standards shall be maintained for every consumer receiving professional support services. In addition to the plan of care, the record shall contain: appropriate identifying information; name of physician; all medications and treatments; signed and dated clinical notes. Clinical notes shall be written the day on which service is rendered and incorporated no less often than weekly; copies of summary reports shall be sent to the physician; and a discharge summary shall be dated and signed within 7 days of discharge.

(b) All medical records, either in written, electronic, graphic or other acceptable form, must be retained in their original or legally reproduced form for a minimum period of at least ten (10) years after which such records may be destroyed. However, in cases of consumers under mental disability or minority, their complete agency records shall be retained for the period of minority or known mental disability, plus one (1) year, or ten (10) years following the discharge of the consumer, whichever is longer. Records destruction shall be accomplished by burning, shredding or other effective method in keeping with the confidential nature of the contents. The destruction of records must be made in the ordinary course of business, must be documented and in accordance with the agency's policies and procedures, and no record may be destroyed on an individual basis.

(c) Even if the agency discontinues operations, records shall be maintained as mandated by this chapter and the Tennessee Medical Records Act (T.C.A. §§ 68-11-308). If a consumer is transferred to another health care facility or agency, a copy of the record or an abstract shall accompany the consumer when the agency is directly involved in the transfer.

(d) Medical records information shall be safeguarded against loss or unauthorized use. Written procedures shall govern use and removal of records and conditions for release of information. The consumer's written consent shall be required for release of information when the release is not otherwise authorized by law.

(e) For purposes of this rule, the requirements for signature or countersignature by a physician or other person responsible for signing, countersigning or authenticating an entry may be satisfied by the electronic entry by such person of a unique code assigned exclusively to him or her, or by entry of other unique electronic or mechanical symbols, provided that such person has adopted same as his or her signature in accordance with established protocol or rules.

(Rule 1200-8-34-.06, continued)

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-209, and 68-11-304.* ***Administrative History:*** *Original rule filed January 24, 2003; effective April 9, 2003.*

1200-8-34-.07 RESERVED.

1200-8-34-.08 RESERVED.

1200-8-34-.09 RESERVED.

1200-8-34-.10 INFECTIOUS AND HAZARDOUS WASTE.

(1) Each agency must develop, maintain and implement written policies and procedures for the definition and handling of its infectious and hazardous waste. These policies and procedures must comply with the standards of this rule and all other applicable state and federal regulations.

(2) The following waste shall be considered to be infectious waste:

(a) Waste human blood and blood products such as serum, plasma, and other blood components;

(b) All discarded sharps (including but not limited to, hypodermic needles, syringes, pasteur pipettes, broken glass, scalpel blades) used in consumer care; and

(c) Other waste determined to be infectious by the agency in its written policy.

(3) Waste must be packaged in a manner that will protect waste handlers and the public from possible injury and disease that may result from exposure to the waste. Such packaging must provide for containment of the waste from the point of generation up to the point of proper treatment or disposal. Packaging must be selected and utilized for the type of waste the package will contain, how the waste will be treated and disposed, and how it will be handled and transported prior to treatment and disposal.

(a) Contaminated sharps must be directly placed in leakproof, rigid and puncture-resistant containers which must then be tightly sealed.

(b) Infectious and hazardous waste must be secured in fastened plastic bags before placement in a garbage can with other household waste.

(c) Reusable containers for infectious waste must be thoroughly sanitized each time they are emptied, unless the surfaces of the containers have been completely protected from contamination by disposable liners or other devices removed with the waste.

(4) After packaging, waste must be handled, transported and stored by methods ensuring containment and preserving of the integrity of the packaging, including the use of secondary containment where necessary.

(5) Waste must be stored in a manner which preserves the integrity of the packaging, inhibits rapid microbial growth and putrefaction, and minimizes the potential of exposure or access by unknowing persons. Waste must be stored in a manner and location which affords protection from animals, precipitation, wind and direct sunlight, does not present a safety hazard, does not provide a breeding place or food source for insects or rodents and does not create a nuisance.

(Rule 1200-8-34-.10, continued)

(6) In the event of spills, ruptured packaging, or other incidents where there is a loss of containment of waste, the agency must ensure that proper actions are immediately taken to:

(a) Isolate the area;

(b) Repackage all spilled waste and contaminated debris in accordance with the requirements of this rule; and,

(c) Sanitize all contaminated equipment and surfaces appropriately.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, and 68-11-209.* ***Administrative History:*** *Original rule filed January 24, 2003; effective April 9, 2003.*

1200-8-34-.11 RECORDS AND REPORTS.

(1) The agency shall retain legible copies of the following records and reports for thirty-six (36) months following their issuance. They shall be maintained in a single file and shall be made available for inspection during normal business hours to any person who requests to view them:

(a) Department licensure and fire safety inspections and surveys;

(b) Centers for Medicare and Medicaid Services (CMS) surveys and inspections, if any;

(c) Orders of the Commissioner or Board, if any; and

(d) Comptroller of the Treasury's audit report and finding, if any.

(2) Unusual events shall be reported by the agency to the Department of Health in a format designed by the Department within seven (7) business days of the date of the identification of the abuse of a consumer or an unexpected occurrence or accident that results in death, life threatening or serious injury to a consumer.

(a) The following represent circumstances that could result in an unusual event that is an unexpected occurrence or accident resulting in death, life threatening or serious injury to a consumer, not related to a natural course of the consumer's illness or underlying condition. The circumstances that could result in an unusual event include, but are not limited to:

1. medication errors;

2. aspiration in a non-intubated consumer related to conscious/moderate sedation;

3. intravascular catheter related events including necrosis or infection requiring repair or intravascular catheter related pneumothorax;

4. volume overload leading to pulmonary edema;

5. blood transfusion reactions, use of wrong type of blood and/or delivery of blood to the wrong consumer;

6. perioperative/periprocedural related complication(s) that occur within 48 hours of the operation or the procedure, including a procedure which results in any new central neurological deficit or any new peripheral neurological deficit with motor weakness;

(Rule 1200-8-34-.11, continued)

7. burns of a second or third degree;

8. falls resulting in radiologically proven fractures, subdural or epidural hematoma, cerebral contusion, traumatic subarachnoid hemorrhage, and/or internal trauma, but does not include fractures resulting from pathological conditions; and

9. procedure related incidents, regardless of setting and within thirty (30) days of the procedure and includes readmissions, which include:

   (i) procedure related injury requiring repair or removal of an organ;

   (ii) hemorrhage;

   (iii) displacement, migration or breakage of an implant, device, graft or drain;

   (iv) post operative wound infection following clean or clean/contaminated case;

   (v) any unexpected operation or re-operation related to the primary procedure;

   (vi) hysterectomy in a pregnant woman;

   (vii) ruptured uterus;

   (viii) circumcision;

   (ix) incorrect procedure or incorrect treatment that is invasive;

   (x) wrong patient/wrong site surgical procedure;

   (xi) unintentionally retained foreign body;

   (xii) loss of limb or organ, or impairment of limb if the impairment is present at discharge or for at least two (2) weeks after occurrence;

   (xiii) criminal acts;

   (xiv) suicide or attempted suicide;

   (xv) elopement from the agency;

   (xvi) infant abduction, or infant discharged to the wrong family;

   (xvii) adult abduction;

   (xviii) rape;

   (xix) consumer altercation;

   (xx) consumer abuse, consumer neglect, or misappropriation of consumer funds;

   (xxi) restraint related incidents; or

   (xxii) poisoning occurring within the agency.

(b) Specific incidents that might result in a disruption of the delivery of professional support services at the agency shall also be reported to the department, on the unusual event form, within seven (7) days after the agency learns of the incident. These specific incidents include the following:

1. strike by the staff at the agency;

2. external disaster impacting the agency;

3. disruption of any service vital to the continued safe operation of the agency or to the health and safety of its consumers and personnel; and

4. fires at the agency which disrupt the provision of consumer care services or cause harm to consumers or staff, or which are reported by the agency to any entity, including but not limited to a fire department, charged with preventing fires.

(c) For professional support services provided in a "home" setting, only those unusual events actually witnessed or known by the person delivering services are required to be reported.

(d) Within forty (40) days of the identification of the event, the agency shall file with the department a corrective action report for the unusual event reported to the department. The department's approval of a Corrective Action Report will take into consideration whether the agency utilized an analysis in identifying the most basic or casual factor(s) that underlie variation in performance leading to the unusual event by (a) determining the proximate cause of the unusual event, (b) analyzing the systems and processes involved in the unusual event, (c) identifying possible common causes, (d) identifying potential improvements, and (e) identifying measures of effectiveness. The corrective action report shall either: (1) explain why a corrective action report is not necessary; or (2) detail the actions taken to correct any error identified that contributed to the unusual event or incident, the date the corrections were implemented, how the agency will prevent the error from recurring in the future and who will monitor the implementation of the corrective action plan.

(e) The department shall approve in writing, the corrective action report if the department is satisfied that the corrective action plan appropriately addresses errors that contributed to the unusual event and takes the necessary steps to prevent the recurrence of the errors. If the department fails to approve the corrective action report, then the department shall provide the agency with a list of actions that the department believes are necessary to address the errors. The agency shall be offered an informal meeting with the Commissioner or the Commissioner's representative to attempt to resolve any disagreement over the corrective action report. If the department and the agency fail to agree on an appropriate corrective action plan, then the final determination on the adequacy of the corrective action report shall be made by the Board after a contested case hearing.

(f) The event report reviewed or obtained by the department shall be confidential and not subject to discovery, subpoena or legal compulsion for release to any person or entity, nor shall the report be admissible in any civil or administrative proceeding other than a disciplinary proceeding by the department or the appropriate regulatory board. The report is not discoverable or admissible in any civil or administrative action except that information in any such report may be transmitted to an appropriate regulatory agency having jurisdiction for disciplinary or license sanctions against the impacted agency. The department must reveal upon request its awareness that a specific event or incident has been reported.

(Rule 1200-8-34-.11, continued)

(g) The department shall have access to agency records as allowed in Title 68, Chapter 11, Part 3. The department may copy any portion of an agency medical record relating to the reported event unless otherwise prohibited by rule or statute. This section does not change or affect the privilege and confidentiality provided by T.C.A. §63-6-219.

(h) The department, in developing the unusual event report form, shall establish an event occurrence code that categorizes events or specific incidents by the examples set forth above in (a) and (b). If an event or specific incident fails to come within these examples, it shall be classified as "other" with the agency explaining the facts related to the event or incident.

(i) This does not preclude the department from using information obtained under these rules in a disciplinary action commenced against an agency, or from taking a disciplinary action against an agency. Nor does this preclude the department from sharing such information with any appropriate governmental agency charged by federal or state law with regulatory oversight of the agency. However, all such information must at all times be maintained as confidential and not available to the public. Failure to report an unusual event, submit a corrective action report, or comply with a plan of correction as required herein may be grounds for disciplinary action pursuant to T.C.A. §68-11-207.

(j) The affected consumer and/or the consumer's family, as may be appropriate, shall also be notified of the event or incident by the agency.

(k) During the second quarter of each year, the Department shall provide the Board an aggregate report summarizing by type the number of unusual events and incidents reported by agencies to the Department for the preceding calendar year.

(l) The Department shall work with representatives of agencies subject to these rules, and other interested parties, to develop recommendations to improve the collection and assimilation of specific aggregate health care data that, if known, would track health care trends over time and identify system-wide problems for broader quality improvement. The goal of such recommendations should be to better coordinate the collection of such data, to analyze the data, to identify potential problems and to work with agencies to develop best practices to remedy identified problems. The Department shall prepare and issue a report regarding such recommendations.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-207, 68-11-209, 68-11-210, and 68-11-211.* ***Administrative History:*** *Original rule filed January 24, 2003; effective April 9, 2003.*

1200-8-34-.12 CONSUMER RIGHTS.

(1) Each consumer has at least the following rights:

(a) To privacy in treatment and personal care;

(b) To have appropriate assessment and management of pain;

(c) To be involved in the decision making and all aspects of their care;

(d) To be free from mental and physical abuse. Should this right be violated, the agency must notify the Department within five (5) business days and the Tennessee Department of Human Services, Adult Protective Services as required by T.C.A. §71-6-101 et seq.;

(Rule 1200-8-34-.12, continued)

(e) To refuse treatment. The consumer must be informed of the consequences of that decision, and the refusal and its reason must be reported to the physician and documented in the medical record;

(f) To refuse experimental treatment and drugs. The consumer's written consent for participation in research must be obtained and retained in his or her medical record; and

(g) To have his or her records kept confidential and private. Written consent by the consumer must be obtained prior to release of information except to persons authorized by law. If the consumer is mentally incompetent, written consent is required from the consumer's legal representative. The agency must have policies to govern access and duplication of the consumer's record.

(2) Each consumer has a right to self-determination, which encompasses the right to make choices regarding life-sustaining treatment, including resuscitative services. This right of self-determination may be effectuated by an advance directive.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, and 68-11-209.* ***Administrative History:*** *Original rule filed January 24, 2003; effective April 9, 2003.*

1200-8-34-.13 RESERVED.

1200-8-34-.14 RESERVED.